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10/032,659

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EXAMINER

WOO, JULIAN W

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/032,659
Filing Date: October 25, 2001
Appellant(s): KRAMER ET AL.

Gunther O. Hanke
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on October 21, 2009 appealing from the Office action mailed on August 13, 2008.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: Claims 1, 3-10, 14-16, 22-24, 26-29, and 41-45 are pending and are under final rejection. Claims 1, 9, 14-16, 22, 26-29, and 41-45 are being appealed.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,954,724

DAVIDSON

9-1999

5,843,175

FRANTZEN

12-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 9, 14-16, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (5,954,724). Davidson discloses the invention substantially as claimed. Davidson discloses, at least in figures 1A and 1B and in col. 8, lines 21-25; col. 11, line 33 to col. 12, line 40; a medical device or stent (10) including a metal alloy substrate having a fine grain size, where the substrate is a titanium based alloy, and where the stent is configured with a plurality of struts or elongate elements. However, Davidson does not disclose that the average grain size is in the range of one to ten microns, that the number of grains across a strut thickness is in the range of five to fifteen, and that the number of grains across an element thickness is more than six. Nevertheless, Davidson discloses that the alloy substrate can be mechanically worked "to optimize grain size" (and inherently, grain number, since the grain size affects the

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number of grains within a given device configuration). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size or number the grains in the substrate as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of grain size and/or number) involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 22 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (5,843,175) in view of Davidson (5,954,724). Frantzen discloses the invention substantially as claimed. Frantzen discloses, at least in figures 1 and 5 and in col. 8, lines 30-63; an intravascular stent comprising a metal alloy substrate. Frantzen discloses that the stent includes a plurality of interconnected cylindrical rings or a plurality of struts or elongate elements (e.g. 20 or 120) and straight links (e.g., 50 or 150) or undulating links (e.g., 180). However, Frantzen does not disclose that the substrate has an average grain size in the range of one to ten microns or about five microns. Davidson teaches, at least in figures 1A and 1B and in col. 8, lines 21-25; col. 11, line 33 to col. 12, line 40; a stent (10) including a metal alloy substrate having a fine grain size. However, Davidson also does not disclose that the average grain size is in the range of one to ten microns or about five microns. Nevertheless, Davidson discloses that the alloy substrate can be mechanically worked "to optimize grain size." Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size or number the grains in the substrate as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art,

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discovering the optimum or workable ranges (of grain size) involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

(10) Response to Argument

Appellant's allegations; in paragraph VII, Grounds I and II, of the brief; that the Examiner is "inaccurate" in the assertion that Davidson teaches a medical device having a "fine grain structure," and that Davidson "does not suggest that grain size would effect strength and toughness [of the alloy of the device]," are incorrect. Indeed, Davidson suggests, in col. 1, lines 46-49, that "[a]lloy strength is achieved by aging to precipitate the alpha phase or by cold working," where the "alpha phase" is a state of the alloy having a fine grain structure. Davidson further teaches, at least in col. 6, lines 47-52 and col. 7, lines 8-14, that it is within the knowledge of one of ordinary skill in the art that strength, elastic modulus and toughness for a metal alloy can be determined according to the use of known materials and production techniques. Among the techniques, Davidson teaches, in col. 8, lines 21-25, that an alloy can be "hot or cold mechanically worked to optimize grain size," where cold working, for instance, "in the softer, lower-modulus-as-quenched condition can further reduce modulus as well as increase strength." Again, as suggested by Davidson, this working of the alloy for increased strength produces an alpha phase, an inherent state of fine-grain structure. In short, Davidson is teaching that grain size and the mechanical properties of an alloy can be intentionally varied according to the desired performance characteristics for the alloy, the composition of the alloy, and the manufacturing methods for producing the alloy. Davidson does not specify an optimal grain size or the range of grain size as

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claimed, for Davidson is only teaching the general conditions of the claims. Davidson allows for the discovery of an optimal or workable range of fine grain size by one with only routine skill in the art. The range of grain size may obviously include one to ten microns, as claimed, if such a range is discovered to be appropriate (i.e., optimal or workable) for a particular medical device. Also obviously, one of ordinary skill would be motivated to discover a fine grain size and an alloy's mechanical properties, so that a medical device would not unduly fail under mechanical stress or known load conditions that could cause, as suggested by the Appellant, "cracking and/or heavy slip band formation." As taught by Davidson, one of ordinary skill in the art would select a known alloy, worked to a fine grain structure ("alpha phase") and use it in a medical device that would have the strength to withstand the loading in a patient's body.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Julian W. Woo/
Primary Examiner, Art Unit 3773

Conferees:

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773

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Supervisory Patent Examiner, Art Unit 3753